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10/536,502	12/14/2005	Chris D. Geddes	014835-101.02-029	6557
24239 7590 01/13/2009 MOORE & VAN ALLEN PLLC			EXAMINER	
P.O. BOX 13706 Research Triangle Park, NC 27709			BERTAGNA, ANGELA MARIE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/536,502 GEDDES ET AL. Office Action Summary Examiner Art Unit ANGELA BERTAGNA 1637 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 07 August 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.4-10.12-16 and 18-27 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1.4-10.12-16 and 18-27 is/are rejected. 7) Claim(s) 4.9 and 23 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date ______.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Status of the Application

 Applicant's response filed on August 7, 2008 is acknowledged. Claims 1, 4-10, 12-16, and 18-27 are currently pending. In the response, Applicant amended claims 1, 5, 18, and 23.

The rejection of claims 1, 4-10, 12-15, 18, and 23 under 35 U.S.C. 112, second paragraph has been withdrawn in view of the Applicant's amendments to the claims.

The following are new grounds of rejection. Applicant's arguments that remain relevant to the new grounds of rejection have been fully considered, but they were not persuasive for the reasons set forth in the "Response to Arguments" section. Any previously made rejections not reiterated below have been withdrawn. Since the new grounds of rejection presented below were not necessitated by Applicant's amendment, this Office Action is made NON-FINAL.

Claim Objections

- 2. Claims 4, 9, and 23 are objected to because of the following informalities:
 - (a) Claim 4 contains a typographical error in line 3 where "the a" is recited.
- (b) Claims 9 and 23 are grammatically incorrect. Replacing "high stringent" with either "highly stringent" or "high stringency" is suggested. Also, claim 9 depends from a canceled claim – claim 2.

Appropriate correction is required.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 4-10, 12-16, and 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. (WO 97/27317 A1; newly cited) in view of Gryczynski et al. (Photonics Spectra (October 2001) 35(10): 96, 97, 99-102, 104; newly cited) and further in view of Cao et al. (Journal of the American Chemical Society (July 2001) 123: 7961-7962; newly cited) and further in view of Qi et al. (Applied and Environmental Microbiology (2001) 67(8): 3720-3727; cited previously).

These claims are drawn to a method for detecting *Bacillus anthracis* in a sample. The method comprises hybridizing a sample suspected of containing *Bacillus anthracis* nucleic acids

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to an oligonucleotide immobilized on a layer of immobilized metal particles followed by hybridizing a fluorescently labeled oligonucleotide to the hybridized duplex.

Lockhart teaches methods of detecting target nucleic acids via array hybridization (see abstract and page 3, line 5 - page 6, line 12).

Regarding claims 1 and 16, the method of Lockhart comprises:

- (a) providing surface-immobilized capture nucleotide sequence probe complementary to a first portion of a target nucleic acid (see page 71, lines 1-14; see also Figures 12 and 13)
- (b) contacting a sample and the capture nucleotide sequence probe, thereby binding any target nucleic acids that are complementary to the capture nucleotide sequence probe (page 71, lines 1-14 and Figures 12-13)
- (c) contacting any bound target nucleic acids with a free nucleotide sequence probe, wherein the free nucleotide sequence probe has an affinity for a second portion of the target nucleic acid and has a fluorophore attached thereto (see page 71, lines 21-28, page 72, lines 23-31, and Figures 12-13; pages 36-39 teach that the label may be a fluorophore)
- (d) identifying the target nucleic acid by fluorescence emission resulting from excitation of the fluorophore following irradiation (see page 73, lines 9-14 and pages 69-70).

Regarding claims 6, 7, 21, and 22, Lockhart teaches detecting fluorescence emission with a device comprising a fluorescent scanner (pages 69-70).

Regarding claim 8, Lockhart teaches covalent immobilization of the capture nucleotide sequence probe to the surface (page 8, lines 20-23).

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Regarding claims 9 and 23, Lockhart teaches binding the capture and free nucleotide sequence probes to the target nucleic acid under highly stringent hybridization conditions (pages 66-67).

Regarding claims 12, 14, 25, and 27, Lockhart teaches the use of a fluorophore having a low quantum yield, specifically rose bengal (see page 38, line 21).

Regarding claims 13 and 26, Lockhart teaches the use of fluorophores that can undergo two-photon excitation (see page 37, line 2, where fluorescein and rhodamine are taught).

Lockhart does not teach that the immobilized capture probes are immobilized to metal particles or a metal layer on a substrate as required by claims 1 and 16, respectively. Also, Lockhart does not teach that the free nucleotide sequence probe further comprises a metal colloid attached thereto for sandwiching the fluorophore between the metal colloid and the metallized substrate as required by claims 15 and 16. Lockhart also does not teach detection of *Bacillus anthracis* as required by claims 1 and 18.

Gryczynski teaches a method for increasing the fluorescence of a fluorophore using metal particles (page 96).

Regarding claims 1, 15, and 16, Gryczynski teaches that "Silver particles can have several beneficial effects on fluorophore brightness, suggesting improvements in applications such as DNA analysis (Figure 2)." Gryczynski teaches that the beneficial effects include increased photostability, decreased lifetime, increased quantum yield, and improved detectability (see Figure 2, page 96, column 1, and Table 1). Gryczynski also teaches that the intrinsic fluorescence from DNA and the extrinsic fluorescence from a fluorophore bound to DNA can be

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enhanced by sandwiching the fluorophore between metal particles (see Figures 5, 7, & 8 and pages 101-102).

Regarding claims 4 and 19, Gryczynski teaches that the distance between the fluorophore and the metal particle should be between about 50 and about 200 Angstroms (see page 99, column 2). This range overlaps with the claimed range of about 50 Angstroms to about 500 Angstroms. Gryczynski further states, "There will be a zone near the surface where the effects are maximal (page 99, column 2)."

Regarding claims 5 and 20, Gryczynski teaches the use of silver particles (see Figures 2-5, 7 and 8, for example).

Regarding claims 6, 7, 21, and 22, Gryczynski teaches detecting fluorescence emission using a detection device comprising a spectrometer (page 97 and Figure 3, for example).

Regarding claims 10 and 24, Gryczynski teaches irradiating the fluorophore using a single photon or a two-photon excitation means (see pages 99, 102, and 103 and Table 1).

Regarding claims 12-14 and 25-27, Gryczynski teaches using a fluorophore with a low quantum yield, such as Rhodamine B or rose bengal (see Figure 3 and page 100).

Gryczynski does not teach immobilization of nucleic acids onto the metal particles as required by claims 1, 8 and 16. Gryczynski also does not teach detection of *Bacillus anthracis* nucleic acids.

Cao teaches a method for synthesizing oligonucleotides modified with silver particles covalently bound to the 5' or 3' terminus (page 7961 and Figure 2). Cao teaches that these oligonucleotides may be used in nucleic acid hybridization assays (page 7962 and Figure 2).

Cao does not teach detection of Bacillus anthracis nucleic acids.

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Qi teaches a method for detecting Bacillus anthracis in a sample using PCR. Regarding this pathogen, Qi stated, "Bacillus anthracis is a causal agent of anthrax, a serious and often fatal infection of livestock and humans. It is considered one of the most effective biological weapons of mass destruction because of its highly pathogenic nature and spore-forming capability and has attracted attention due to its potential use as a biological warfare agent (page 3720, column 1).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to apply the teachings of Gryczynski to the method of Lockhart. Specifically, an ordinary artisan would have been motivated to immobilize the capture oligonucleotides on a layer of immobilized metal particles positioned on the surface of the array and additionally attach a metal colloid to the fluorophore-containing detection probe so as to sandwich the fluorophore between two metal layers, since Gryczynski taught that such sandwiching of low quantum yield fluorophores, such as rose bengal, results in increased photostability, decreased lifetime, increased quantum yield, and improved detectability (see above). An ordinary artisan would have had a reasonable expectation of success in covalently attaching the capture and detection probes of Lockhart to metal colloids, since Cao taught methods of covalently attaching silver particles to oligonucleotides (page 7961). Finally, regarding the ranges set forth in claims 4 and 19, as noted in MPEP 2144.05, "In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPO 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPO2d 1934 (Fed. Cir. 1990)."

An ordinary artisan also would have been motivated to apply the method resulting from the combined teachings of Lockhart, Gryczynski, and Cao to the detection of any clinically

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relevant nucleic acid, such as nucleic acids from the pathogenic microorganism, *Bacillus* anthracis, which Qi taught is "one of the most effective biological weapons of mass destruction (page 3720, column 1)." An ordinary artisan would have had a reasonable expectation of success in designing capture and free nucleotide sequence probes to detect *Bacillus anthracis*, since Qi taught that the complete *Bacillus anthracis rpoB* gene sequence was publicly available and successfully designed nucleic acid primers and probes from this sequence (see pages 3722-3724). Thus, the methods of claims 1, 4-10, 12-16, and 18-27 are *prima facie* obvious in view of the combined teachings of Lockhart, Gryczynski, Cao, and Qi.

5. Claims 1, 4-10, 12-16, and 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cao et al. (Science (2002) 297: 1536-1540; cited previously) as evidenced by Malicka et al. (Biopolymers (2003) 72(2): 96-104; cited previously) and Lukomska et al. (Biochemical and Biophysical Research Communications (2005) 328: 78-84; cited previously) in view of Lakowicz (US 2002/0160400 A1; cited previously and hereafter "Lakowicz I") and further in view of Lakowicz et al. (Biochemical and Biophysical Research Communications (2001) 286: 875-879; cited previously and hereafter "Lakowicz II").

These claims are drawn to a method for detecting *Bacillus anthracis* in a sample. The method comprises hybridizing a sample suspected of containing *Bacillus anthracis* nucleic acids to an oligonucleotide immobilized on a layer of immobilized metal particles followed by hybridizing a fluorescently labeled oligonucleotide to the hybridized duplex.

Cao teaches a sandwich assay for detecting target nucleic acid from a pathogen in a sample (see abstract and Scheme 1 on page 1537).

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Regarding claims 1 and 16, the method of Cao comprises:

- (a) providing surface-immobilized capture nucleotide sequence probe complementary to a first portion of a nucleotide sequence in the pathogen (see Scheme 1 and page 1537, column 1, paragraph 2)
- (b) contacting the sample and the capture nucleotide sequence probe, thereby binding any pathogen nucleic acids that are complementary to the capture nucleotide sequence probe (see Scheme 1 and page 1537, column 1, paragraph 2)
- (c) contacting any bound pathogen nucleic acids with a free nucleotide sequence probe, wherein the free nucleotide sequence probe has an affinity for a second portion of the pathogen nucleic acid and has a fluorophore attached thereto (see Scheme 1 and page 1537, column 1, paragraph 2)
- (d) identifying the pathogen using surface enhanced Raman spectroscopy (see Scheme 1 and pages 1537-1538).

Further regarding claim 1 and also regarding claim 18, Cao teaches using the method to detect *Bacillus anthracis* (page 1538, column 1).

Regarding claim 8, Cao teaches covalent immobilization of the capture nucleotide sequence probe to the surface (see Scheme 1 and page 1537, column 1).

Regarding claims 9 and 23, Cao teaches binding the capture and free nucleotide sequence probes to the pathogen nucleic acid under highly stringent hybridization conditions (page 1539).

Regarding claims 12 and 25, as evidenced by Malicka at page 100, column 1, the Cy3 fluorophore taught by Cao has a low quantum yield.

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Regarding claims 13 and 26, as evidenced by Lukomska at pages 78-80, the Cy3 fluorophore taught by Cao can undergo two-photon excitation.

Cao does not teach that the immobilized capture probes are immobilized to metal particles or a metal layer on a substrate as required by claims 1 and 16, respectively. Also, Cao teaches detection using Raman spectroscopy rather than fluorescence spectroscopy. Finally, Cao does not teach that the free nucleotide sequence probe further comprises a metal colloid attached thereto for sandwiching the fluorophore between the metal colloid and the metallized substrate as required by claims 15 and 16.

Lakowicz I teaches a method for increasing the fluorescence of a fluorophore using metal particles (see abstract and paragraph 13).

Regarding claims 1, 15, and 16, Lakowicz I teaches that the fluorescence intensity of a fluorophore conjugated to a biomoleucle, such as DNA or RNA, can be increased at least 80 to 140 fold by positioning the fluorophore near a metal particle (paragraphs 13, 18, 71, and 84). Lakowicz I provides an example of this increase in fluorescence intensity in Figure 3, Figure 8, Figure 19, and paragraphs 114-116, 122, and 131-132, where the intensity of a fluorophore is increased by sandwiching between silver island films. Lakowicz I further teaches that may be substituted for the silver island films (paragraph 71).

Regarding claims 4 and 19, Lakowicz I teaches that the distance between the fluorophore and the metal particle should be optimized and separation distances between about 50 and about 2000 Angstroms, about 50 to about 200 Angstroms, and about 50 to about 300 Angstroms are particularly useful (paragraphs 71-72).

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Regarding claims 5 and 20, Lakowicz I teaches the use of silver particles (paragraph 71) or gold particles (paragraph 70).

Regarding claims 6, 7, 21, and 22, Lakowicz I teaches detecting fluorescence emission using a detection device comprising a spectrometer (paragraph 76) or a fluorescent scanner (paragraph 91).

Regarding claim 8, Lakowicz I teaches covalent immobilization to the metal particles (paragraph 72).

Regarding claims 10 and 24, Lakowicz I teaches irradiating the fluorophore using a single photon (paragraph 149) or a two-photon excitation means (paragraphs 100 and 147).

Regarding claims 12-14 and 25-27, Lakowicz I teaches using a fluorophore with a low quantum yield, such as Rhodamine B, rose bengal, or fluorescein isothiocyanate (paragraphs 64, 66, and 84). Lakowicz I teaches fluorophores with a low quantum yield only fluoresce when they are adjacent to a metal particle (paragraph 105). Lakowicz I further teaches that these fluorophores can undergo two-photon excitation (paragraph 147).

Lakowicz II teaches that the intrinsic fluorescence from DNA and the extrinsic fluorescence from a fluorophore conjugated to a DNA molecule can be enhanced by sandwiching the fluorophore between metal particles (see abstract, page 875, and page 877, and Figure 3). Lakowicz further teaches that the fluorescence enhancement in the presence of metal particles is analogous to surface-enhanced Raman spectroscopy (page 878).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to apply the teachings of Lakowicz I and Lakowicz II to the method of Cao.

Specifically, an ordinary artisan would have been motivated to sandwich the Cy3 fluorophore

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between metal particles, such as a metal colloid, and measure fluorescence emission from the fluorophore, as taught by Lakowicz I, since Lakowicz I and Lakowicz II taught that the fluorescence signal of a low quantum yield fluorophore could be enhanced by sandwiching the fluorophore between metal particles (see above). Since Lakowicz II taught that fluorescence enhancement by metal particles was analogous to surface-enhanced Raman spectroscopy (page 878) and since the methods of Lakowicz I and Lakowicz II were directed to enhancing the fluorescence of an extrinsic fluorophore conjugated to a nucleic acid (see above), an ordinary artisan would have been motivated to utilize either of these analogous detection methods to detect *Bacillus anthracis* in the method of Cao with a reasonable expectation of success. Thus, the methods of claims 1, 4-10, 12-16, and 18-27 are *prima facie* obvious over Cao as evidenced by Malicka and Lukomska in view of Lakowicz I and further in view of Lakowicz II.

Response to Amendment

The declaration made by Dr. Chris Geddes filed on August 7, 2008 under 37 CFR 1.131
 has been considered but is ineffective to overcome the Cao reference (Science (August 2002)
 297: 1536-1540).

As an initial matter, the declaration is insufficient, because it has been signed by only one of the three inventors named on the instant application. As noted in MPEP 715.04 I, a declaration under 37 CFR 1.131 may be submitted by either: (A) all inventors of the claimed subject matter; or (B) less than all named inventors where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. In this case, Applicant has not established that less than all of the named inventors invented the

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subject matter of the instant claims, and therefore, a declaration signed by only one of the inventors is not sufficient to overcome the previously made rejection citing the Cao reference.

It is also noted that the evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Cao reference. The evidence submitted in the declaration consists of a PowerPoint slide depicting the two assay methods. This evidence is sufficient to establish conception of the claimed invention prior to the effective date of the Cao reference. However, the evidence does not establish a reduction to practice, because it provides no indication that the assays described in the PowerPoint slide were ever performed successfully. MPEP 2138.05 II & III state that such testing is required to establish an actual reduction to practice, particularly in unpredictable arts, such as biochemistry.

Since the declaration filed under 37 CFR 1.131 is insufficient to overcome the Cao reference, the rejection of claims 1, 4-10, 12-16, and 18-27 under 35 U.S.C. 103(a) as being unpatentable over Cao as evidenced by Malicka and Lukomska in view of Lakowicz I and further in view of Lakowicz II of has been maintained.

Response to Arguments

7. Applicant's arguments, see pages 8-10, filed on August 7, 2008, regarding the rejection of claims 1, 5, 9, 10, 12, and 13 under 35 U.S.C. 103(a) as being unpatentable in view of the combined teachings of Vo-Dinh, Doukas, Letuta, and Qi have been fully considered and are persuasive. This rejection has been withdrawn.

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Applicant's arguments regarding the rejection of claims 1, 4-10, 12-16, and 18-27 under 35 U.S.C. 103(a) as being unpatentable over Cao as evidenced by Malicka and Lukomska in view of Lakowicz I and further in view of Lakowicz II have been fully considered, but they were not persuasive.

Applicant first argues that inclusion of the Malicka and Lukomska references in the rejection is improper, since these references are post-filing art (see page 11). This argument was not persuasive, because as discussed in the rejection, the Malicka and Lukomska references are only relied upon to establish inherent features present in the teachings of Cao. As noted in MPEP 2112 II, inherency need not be recognized prior to the filing date of the instant application.

Applicant also argues that the declaration made under 37 CFR 1.131 is sufficient to overcome the primary reference cited in the rejection (Cao), which was published on August 30, 2002 (see pages 11-12). This argument was not persuasive, because the declaration was insufficient to overcome the Cao reference. As discussed above, the declaration was not signed by either all of the inventors or only those named inventors who have been shown to have invented the subject matter of the claim or claims under rejection. The declaration also has not established a reduction to practice prior to the effective date of the Cao reference.

Applicant also states that US 7,095,502 issued to Lakowicz is commonly owned prior art that only qualifies under 35 U.S.C. 102(e) (see page 12), and therefore, the reference is disqualified as prior art under 35 U.S.C. 103(a). This argument was not persuasive, because the previously made rejection did not cite the '502 patent. The rejection cited Lakowicz (US 2002/0160400 A1), which qualifies as prior art under 35 U.S.C. 102(a) and 35 U.S.C. 102(e).

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Applicant's statements regarding the '502 patent do not disqualify the '400 publication as prior art under 35 U.S.C. 103(a).

Since applicant's arguments were not persuasive, the rejection of claims 1, 4-10, 12-16, and 18-27 under 35 U.S.C. 103(a) as being unpatentable over Cao as evidenced by Malicka and Lukomska in view of Lakowicz I and further in view of Lakowicz II has been maintained.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F. 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.usplo.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

> /Kenneth R Horlick/ Primary Examiner, Art Unit 1637

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